

C Summary

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: **k043415**." (applicant leave blank)

Premarket Notification [510(k)] Summary

[(a)(1)]. The summary contains on the first page, preferably on your letterhead paper, the submitter's name, address, phone and fax numbers, name of contact person, and date the summary was prepared :

Submitter's name : SHIJIAZHUANG WINFUL PLASTIC CO.,LTD
Submitter's address : NO.6 CANGSHI ROAD, JINZHOU CITY,HEBEI, 052260,
P.R. China
Phone number : (86)-311-4320503
Fax number : (86)-311-4336614
Name of contact person: Mr. Yin Mingfei
Date the summary was prepared: Dec.06,2004

[(a)(2)]. The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Device Name: Powder Free Vinyl Patient Examination Gloves, white(non-colored)
Proprietary/Trade name: Powder Free Vinyl Patient Examination Gloves
Other clients private labeling
Common Name: Patient examination glove
Classification Name: Patient examination glove
Device Classification: I
Regulation Number: 21 CFR 880.6250
Panel: General Hospital (80)
Product Code: LYZ

[(a)(3)]. An identification of the legally marketed device to which your firm is claiming substantial equivalence .

Class I* powder free vinyl patient examination gloves , white(non-colored) that meets all of the requirements of ASTM standard D 5250-00^{ed}.

Predicate device : FUGUAN (Brand) Powder-Free Vinyl Patient Examination Gloves, Shijiazhuang Fuguan Plastic Products Co., Ltd.. K032908 .

[(a)(4)] A description of the device

Device Description : powder free vinyl patient examination gloves, white(non-colored) that meets all of the requirements of ASTM standard D 5250-00^{ed}.

[(a)(5)] The summary describes the intended use of the device

Device Intended Use: powder free vinyl patient examination glove, white(non-colored) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

[(a)(6)] A summary of the technological characteristics of new device compared to the predicate device.

The powder free vinyl patient examination gloves, non sterile are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	Standard	Device performance
Dimension	ASTM standard D 5250-00 ^{e4}	Meets
Physical Properties	ASTM standard D 5250-00 ^{e4}	Meets
Freedom from pinholes	21 CFR 800.20	Meets
Powder Residual	ASTM standard D 5250-00 ^{e4}	Meets
	and D6124-01	<2mg/glove
Biocompatibility	Primary Skin Irritation in rabbits	Passes
	Dermal sensitization in the guinea pig	Not a Primary Skin Irritation Passes Not a Dermal sensitization

[(b)(1)] A brief discussion of the nonclinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence .

Powder free vinyl patient examination gloves , white(non-colored) meet requirements per ASTM D5250-00^{e4}, per ASTM D6124-01, per 21 CFR 800.20 and ISO10993-10.

[(b)(2)] A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence .

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

[(b)(3)] The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe,as effective, and performed as well or better than the legally marketed device identified in (a)(3).

It can be concluded that the Powder Free Vinyl Patient Examination Gloves meet the ASTM standard or equivalent standard and FDA requirements for waterleak test on pinhole AQL., meet labeling claims .



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 1 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shijiazhuang Winful Plastic Company Limited
C/O Ms. Chen Yuhong
TUV Rheinland Beijing Office
Unit 707, AVIC Building, No. 10B Central Road,
East 3rd Ring Road,
Chaoyang District, Beijing,
P.R. CHINA 10002

Re: K043475

Trade/Device Name: Powder-Free Vinyl Patient Examination Gloves, White
(Non-Colored)

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LYZ

Dated: December 13, 2004

Received: December 16, 2004

Dear Ms. Yuhong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a large, stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043475

Device Name: POWDER-FREE VINYL PATIENT EXAMINATION GLOVES, WHITE (NON-COLORED)

Indications For Use: **This powder free vinyl patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.**

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sabrina Dot for Lynette Richard, Acting Branch Chief 2/1/05
(Person Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K043475